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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,195	04/01/2004	Johan Frostegard	FROSTEGARD=1B	6441

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,195	FROSTEGARD, JOHAN	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *1-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/720,967.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently claims 1-19 are pending and under consideration.

Priority

2. The first line of the specification should be updated to include US Patent #6,780,605. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included. Please include US Patent #6,780,605.

Drawings

3. No drawings were filed in this application.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 cited the references they have not been considered.

5. The Information Disclosure Statement filed 01 April 2004 has been consider as to the merits prior to first action.

Claim Objections

6. Claims 1-19 are objected to because of the following informalities: Claims 1-19 utilize the acronym PAF. Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim any prior art definition of the abbreviations. The terms should be defined in their first instance. PAF is platelet-activating factor (page 1 of the specification). The initial explanation will convey intended meaning of subsequent abbreviations in the claims. Please define.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "early" in claims 1, 2, and 4 is a relative term, which renders the claim indefinite. The term "early" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Will the measurement indicate atherosclerosis or not? Please remove the term from the claim.

B. Claim 2 is vague and indefinite in utilizing the term "utilizes" because it is not clear if the kit "comprises" or "consists of" several diagnostic indicators including antibodies to PAF and/or antibodies to antigens of PAF antibodies. As recited it is not clear what the kit contains because the claim merely reads on the kits utility. Appropriate correction required.

C. Claims 2, 5-7 and 10 are vague and indefinite in reciting "capable of" because the recitation that an element is capable of performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. It is suggested that this language is removed.

D. Claim 4 is vague and indefinite because it is not clear how a diagnosis of cardiovascular disease will also determine independent disorders like early atherosclerosis, hypertension, and thrombosis. If applicant intends to imply that the kit further detects or measures early atherosclerosis, hypertension, and thrombosis in addition to cardiovascular disease, then that should be clearly recited in the claim. Please clarify.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-23 of copending Application No. 10/814,194 in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988). Both applications are drawn to kits comprising the same reagents (means for determining antibodies to PAF and/or an antigen capable of binding PAF). Although the preambles are directed to different utilities, this is not given patentable weight in the product (kit) claims.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention. See *In re Casey*, 370 F.2d 576, 152 USPQ 235(CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459(CCPA 1963).

Application No. 10/814,194 differs from the instant invention in not specifically teaching a means for determining patients at risk for having cardiovascular and/or early atherosclerosis (correlate PAF concentration to cardiovascular disease and/or early atherosclerosis).

However, Ostermann et al. teach PAF quantification in serum and plasma as well as its correlation/diagnosis (discrimination) in Atherosclerotic patients. See abstract and page 531 2nd paragraph. Thirty-Six health volunteers and 40 atherosclerotic patients were evaluated in the study. Blood samples were analyzed to determine PAF concentration. The results showed a significant increase in serum PAF levels of patients suffering from coronary artery disease. Page 536, last paragraph. The researchers also measured plasma levels. See page 538.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to correlate the measurement of PAF concentrations in serum and plasma patients with cardiovascular disease such as atherosclerosis as taught by Ostermann et al. in the kit of Application No. 10/814,194 because Osterman et al. taught the critical role of PAF in myocardial infarction/atherosclerosis and its accuracy of correctly classifying subjects. See abstract. Ostermann et al. further taught that PAF could discriminate between low and high-risk groups and was an improvement over other commonly utilized discriminators (total cholesterol, VLDL/LDL-cholesterol, apo). See page 537 2nd paragraph.

One having ordinary skill in the art would have been motivated to do this because the early detection of such disorders is both beneficial in possible prevention and treatment of the disease.

10. This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1-2 and 5-7 are rejected under 35 U.S.C.103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879).

Barquinero et al. teach an ELISA assay to measure antibodies against platelet-activating factor (PAF) in patients with autoimmune diseases. Specifically blood sample from patients with SLE (systemic lupus crythematosus), PAPS (antiphospholip syndrome), and syphilis. SLE is vascular diseases (relating to blood vessels). SLE includes severe inflammation of blood vessels (see The signet Mosby medical encyclopedia definition attached). See abstract and page 55 Introduction and page 56 "ELISA technique for anti-PAF".

With respect to the means for determining patients at risk for having cardiovascular disease and/or early atherosclerosis, it is noted that Barquinero et al. teach the measurement of PAF in patients with autoimmune disease such as SLE. SLE includes blood vessel inflammation, which could lead to cardiovascular disease (risk). Since there is no corresponding structure, etc., in the specification to limit the means step or step plus function limitation, an equivalent is any element that performs the specified function.

Although Barquinero et al. teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations. In other words, the reference fails to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Barquinero et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

II. Claims 3-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) and further in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988).

Please see Barquinero et al. in view of Foster et al. as set forth above.

Barquinero et al. in view of Foster et al. differ from the instant invention in not specifically teaching PAF as an indicator for cardiovascular diseases such as atherosclerosis via PAF quantification in serum and plasma.

However, Ostermann et al. teach PAF quantification in serum and plasma as well as its correlation/diagnosis (discrimination) in Atherosclerotic patients. See abstract and page 531 2nd paragraph. Thirty-Six health volunteers and 40 atherosclerotic patients were evaluated in the study. Blood samples were analyzed to determine PAF concentration. The results showed a significant increase in serum PAF levels of patients suffering from coronary artery disease. Page 536, last paragraph. The researchers also measured plasma levels. See page 538.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure PAF concentrations in serum and plasma patients with cardiovascular disease such as atherosclerosis as taught by Ostermann et al. in the method of Barquinero et al. because Osterman et al. teach the critical role of PAF in myocardial infarction/atherosclerosis and its accuracy of correctly classifying subjects. See abstract. Ostermann et al. further teach that PAF could discriminate between low and high-risk groups and was an improvement over other commonly utilized discriminators (total cholesterol, VLDL/LDL-cholesterol, apo). See page 537 2nd paragraph.

One having ordinary skill in the art would have been motivated to do this because the early detection of such disorders is both beneficial in possible prevention and treatment of the disease.

III. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) and further in view of Karasawa et al.(Lipids, Vol. 26, No. 12, 1991, pages 1122-1125).

Please see Barquinero et al. in view of Foster et al. as set forth above.

Barquinero et al. in view of Foster et al. differ from the instant invention in not specifically teaching the detection of various known naturally occurring phospholipids related to PAF(phospholine). These forms include lyosPAF , PC(phosphatidylcholine), and lysoPC(lysophosphatidylcholine).

However, Karasawa et al. disclose systems to detect antibodies to PAF. The reference further evaluates related phospholipids (PC, lysoPC, lysoPAF, PE, PS, PG, PI, PA, SM, and CL. See abstract. Each phospholipids reacts differently with regard to binding antibodies to PAF. In some instances the related phospholipids cross react with PAF antibodies. See page 1123 Results. This cross-reaction could result in erroneous results in PAF antibody levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various known PAF related phospholipids to evaluate cross reactivity and allow for accurate detection of PAF antibodies as taught by Karasawa et al. in the kit of Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) because Karasawa et al. disclosed that these related PAF phospholipids could possible cross-react with PAF. See page 1125.

One having ordinary skill in the art would have been motivated to do this to account for cross-reactivity and provide accurate detection of aPAF (antibodies to PAF).

IV. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) and further in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988) as applied to claims 3-4, and 8-10 above, and further in view of Karasawa et al.(Lipids, Vol. 26, No. 12, 1991, pages 1122-1125).

Please see Barquinero et al. in view of Foster et al. and further in view of Karasawa et al. as set forth above.

Barquinero et al. in view of Foster et al. and further in view of Karasawa et al. differ from the instant invention in not specifically teaching the detection of various known naturally occurring phospholipids related to PAF(phospholine). These forms include lyosPAF , PC(phosphatidylcholine), and lysoPC(lysophosphatidylcholine).

However, Karasawa et al. disclose systems to detect antibodies to PAF. The reference further evaluates related phospholipids (PC, lysoPC, lysoPAF, PE, PS, PG, PI, PA, SM, and CL. See abstract. Each phospholipids reacts differently with regard to binding antibodies to PAF. In some instances the related phospholipids cross react with PAF antibodies. See page 1123 Results. This cross-reaction could result in erroneous results in PAF antibody levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various known PAF related phospholipids to evaluate cross reactivity and allow for accurate detection of PAF antibodies as taught by Karasawa et al. in the kit of Barquinero et al. in view of Foster et al. and further in view of Karasawa et al. because Karasawa et al. disclosed that these related PAF phospholipids could possible cross-react with PAF. See page 1125.

One having ordinary skill in the art would have been motivated to do this to account for cross-reactivity and provide accurate detection of aPAF (antibodies to PAF).

12. For reasons aforementioned, no claims are allowed.

Remarks

13. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Baldo et al. (LIPIDS, Vol26, No.12, 1991, 1136-1139) teach an immunoassay technique to measure PAF

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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